

DETAILED ACTION

Responsive to communication entered 04/19/2011.

Status of Claims

Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are pending. Claims 1, 6 and 7 are amended, and Claims 2-5, 8-11 and 27 are cancelled by Applicant as set forth in the Reply entered 04/19/2011. Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are examined.

Priority

The instant application, 10/599,943, is the 35 U.S.C. 371 filing of PCT/GB05/01369, filed on 04/07/2005, which claims foreign priority to United Kingdom patent application 0408351.5, filed on 04/15/2004.

Withdrawn Objections/Rejections

- I. The rejection of Claims 1, 8-16, 27, 28 and 31 under 35 U.S.C. 102(b) as being anticipated by Short & Whittle, WO 01/031339, as evidenced by WO 98/19161 and Sigma Catalog, 2000-2001, page 337, is withdrawn in view of Applicant's amendment of Claim 1 and cancellation of Claims 8-11 and 27.
- II. The rejection of Claims 2-5, 8-11 and 27 under 35 U.S.C. 102(e) as being anticipated by Short *et al.*, WO 2004/040308 A1, as evidenced by Dako General ELISA Procedure, February 2002, is withdrawn in view of Applicant's cancellation of the claims.
- III. The rejection of Claims 2-5, 8-11 and 27 under 35 U.S.C. 103(a) as being unpatentable over Short & Whittle, WO 01/031339, as evidenced by WO 98/19161, and Sigma Catalog, 2000-2001, page 337, in view of Marchant, WO 94/10938 and Schwarz

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et al. Glycobiology, 2003, vol. 13, No. 11, p. 749-754, is withdrawn in view of Applicant's cancellation of the claims.

IV. The provisional rejection of Claims 2-5, 8-11 and 27 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4-25 and 33-38 of co-pending U.S. Application No. 10/533,063, in view of Schwartz and Sigma; over Claims 85, 87, 90-94, 96, 102, 103, 108, 109 and 112-123 of co-pending U.S. Application No. 10/560,210, in view of Schwartz and Sigma; and over Claims 41, 47-50 and 54 of co-pending U.S. Application No. 10/509,431, in view of Marchant, Schwartz and Sigma is withdrawn in view of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 6, 7, 12-16, 26, 28 and 31 are rejected under 35 U.S.C. 102(e) as being anticipated by **Short et al.**, WO 2004/040308 A1, filed October 29, 2003, published May 13, 2004 (of record), as evidenced by **Dako** General ELISA Procedure, February 2002 (of record).

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The applied reference has a common inventor(s) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

This rejection is maintained from the Office Action mailed 01/19/2011.

The claims, as recited in the sole independent Claim 1, are drawn to a method for the selective disassociation of at least one glycosaminoglycan bound to a plasma polymerized surface of an organic monomer including an allylamine, said method comprising contacting said surface with at least one agent having a salt concentration of about 500 mM NaCl to about 2 M NaCl, wherein said agent provides for selective disassociation of said bound glycosaminoglycan from said plasma polymerized surface. Claims 28, 29 and 31 recite the variable ranges within the claimed range of the salt concentration of Claim 1. Claims 6, 7 and 26 recite glycosaminoglycans. Claims 12 and 13 require the surface to comprise a plasma polymer of a volatile acid. Claim 14 requires the surface to comprise a plasma polymer of a volatile alcohol. Claim 15 requires the surface to comprise a plasma polymer of a volatile amine. Claim 16 requires the surface to comprise a mixture of volatile acid and volatile hydrocarbon.

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Short et al., throughout the publication, and, for example, at pages 6, 8, and 13, teach how to make and use a plasma polymerized surface of an organic monomer, including an allylamine, for immobilization of carbohydrates, polypeptides, genomic DNA, and cells. *Short et al.* at page 3 through page 5; Claims 4-7; 11-12; 15-16; teach the surface comprising volatile acid, volatile amine, volatile alcohol, and volatile hydrocarbon, and the surface comprising a mixture of one or more compounds having functional groups with a hydrocarbon. *Short et al.* at page 1 teach heteropolysaccharide, including glycosaminoglycans, such as, hyaluronan, dermatan sulfate, chondroitin sulfate, heparin, heparan sulphate and keratan sulphate, and homopolysaccharide.

As to recitation “a salt concentration of about 500 mM NaCl to about 2 M NaCl,” *Short et al.* at page 16 teach use of standard ELISA methods to wash the unbound heparin from the allylamine coated microtiter plates. According to MPEP 2131.01, extra references can be used to show the meaning of a term used in the primary reference. **Dako** General ELISA Procedure, February 2002 indicates that 0.15 M and 0.5 M NaCl concentrations are used in the standard coating and washing buffers for ELISA methods. A specific example in the prior art which is within a claimed range, here, 0.5 M NaCl concentration, anticipates the range. MPEP 2131.01.

“[W]hen, as by a recitation of ranges or otherwise, a claim covers several compositions, the claim is anticipated’ if *one* of them is in the prior art.” *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985) (citing *In re Petering*, 301 F.2d 676, 682, 133 USPQ 275, 280 (CCPA 1962)) (emphasis in original).

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Therefore, each and every element of the claims are met by the Short *et al.* reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Short & Whittle**, WO 01/031339, published on May 3, 2001 (of record) as evidenced by **WO 98/19161** (of record), to which Short & Whittle refer to at page 3, lines 12-15, in view of **Marchant**, WO 94/10938 (of record) and **Schwarz *et al.*** *Glycobiology*, 2003, vol. 13, No. 11, p. 749-754 (of record).

This rejection is maintained from the Office Action mailed 01/19/2011.

Short & Whittle, throughout the publication, and, for example, at page 5, line 1; page 8, lines 1-4; page 7, lines 10-14 and 16-17; Claims 8, 11, 13-15, 25; teach how to make and use a plasma polymerized surface of an organic monomer, including an allylamine, for detection of polypeptides, nucleic acids, including DNA and RNA, and cells. Short & Whittle, at page 4, line 21 through page 5, line 6; Claims 16-24; teach the surface comprising volatile acid, volatile amine, volatile alcohol, and volatile hydrocarbon, and the surface comprising a mixture of one or more compounds having functional groups with a hydrocarbon. At page 12, Short & Whittle teach an enzyme

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linked immunosorbent assay (ELISA) for estimating the binding of human immunoglobulin G (IgG) onto the different plasma copolymer surfaces. Short & Whittle teach washing the surfaces with PBS-Tween (page 12, lines 14-15). **WO 98/19161**, to which Short & Whittle refer to at page 3, lines 12-15, indicates that 0.15 M and 0.5 M NaCl concentrations are used in the standard coating and washing buffers for ELISA methods for ELISA methods. See, for example, page 19, line 32; page 22, line 6.

Short & Whittle do not teach glucosaminoglycan and a salt concentration of from more than 500 mM NaCl to about 2 M NaCl.

Marchant, throughout the publication, and, for example, at page 5, line 20 through page 6, line 11; Abstract, teaches a method of modification of the surface of a substrate, such as polyethylene, by plasma polymerizing polar organic monomers, such as N-vinyl-2-pyrrolidone or allyl alcohol, onto the surface of the substrate to provide a film of a plasma generated polymer on the surface. At page 19, lines 5-6, Marchant teaches an attachment of high-affinity heparin onto polyethylene samples surface-modified by plasma polymerization. At page 14, lines 23-35, Marchant teaches that 3 M NaCl linear salt gradient elution of increasing ionic strength was used for column separation of three different heparin fractions with different affinity for antithrombin III: non-adsorbed heparin, low affinity heparin and high-affinity heparin.

Schwarz *et al.* teach a carbohydrate array for specific binding glycan-binding proteins. At page 753, Schwarz *et al.* teach washing the glycan array with high-salt buffer PBS-Tween, supplemented with 2 M NaCl.

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It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to select a salt concentration of about 500 mM NaCl to about 2 M NaCl from the 3 M NaCl linear salt gradient, taught by Marchant, the 2 M NaCl glycan array washing buffer, taught by Schwarz *et al.*, and the 0.137 M - 0.138 M NaCl; 0.15 M and 0.5 M NaCl standard coating and washing buffers for ELISA methods, for the selective disassociation of a glucosaminoglycan from a plasma polymerized surface taught by Short & Whittle. Here, the skilled artisan could have arrived at the claim through routine experimentation on the optimum or workable ranges of the claim.

One of ordinary skill in the art, at the time the invention was made, would have been motivated to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for the selective disassociation of a glucosaminoglycan, because it would be desirable, to re-use the plasma polymerized surface, taught by Short & Whittle, or use it, for example, for investigation of ionic strength of carbohydrate-protein interactions.

One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because NaCl is routinely used in the standard PBS buffers for immunoassays. In addition, as taught by Marchant, use of the 3 M NaCl linear salt gradient elution of increasing ionic strength provides selective separation of carbohydrates, such as heparin polysaccharides.

Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Short & Whittle**, WO 01/031339, published on May 3, 2001 (of record) as evidenced by **WO 98/19161** (of record), to which Short & Whittle refer to at

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page 3, lines 12-15, in view of **Hutchens**, WO 98/59360, published 12/30/1998 (of record), and **Marchant**, WO 94/10938, published 05/26/1994 (of record).

This rejection is maintained from the Office Action mailed 01/19/2011.

Short & Whittle, throughout the publication, and, for example, at page 5, line 1; page 8, lines 1-4; page 7, lines 10-14 and 16-17; Claims 8, 11, 13-15, 25; teach how to make and use a plasma polymerized surface of an organic monomer, including an allylamine, for detection of polypeptides, nucleic acids, including DNA and RNA, and cells. Short & Whittle, at page 4, line 21 through page 5, line 6; Claims 16-24; teach the surface comprising volatile acid, volatile amine, volatile alcohol, and volatile hydrocarbon, and the surface comprising a mixture of one or more compounds having functional groups with a hydrocarbon. At page 12, Short & Whittle teach an enzyme linked immunosorbent assay (ELISA) for estimating the binding of human immunoglobulin G (IgG) onto the different plasma copolymer surfaces. Short & Whittle teach washing the surfaces with PBS-Tween (page 12, lines 14-15). **WO 98/19161**, to which Short & Whittle refer to at page 3, lines 12-15, indicates that 0.15 M and 0.5 M NaCl concentrations are used in the standard coating and washing buffers for ELISA methods for ELISA methods. See, for example, page 19, line 32; page 22, line 6.

Short & Whittle do not teach glucosaminoglycan and a salt concentration of from more than 500 mM NaCl to about 2 M NaCl.

Hutchens, throughout the publication, and, for example, in Abstract, teaches methods of retentate chromatography for resolving analytes in a sample, which

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methods involve adsorbing the analytes to a substrate under a plurality of different selectively conditions, and detecting the analytes retained on the substrate by desorption spectrometry. At page 7, line 9; page 21, line 15; Hutchens teaches the analyte to be an organic biomolecule, such as carbohydrate. At page 33, lines 1-9, Hutchens teaches washing the adsorbent with eluants. At page 33, lines 19-26, Hutchens teaches the use of ionic strength-based salt eluants:

“Eluants which modify the selectivity of the adsorbent with respect to ionic strength include salt solutions of various types and concentrations. The amount of salt solubilized in the eluant solution affects the ionic strength of the eluant and modifies the adsorbent binding ability correspondingly. Eluants containing a low concentration of salt provide a slight modification of the adsorbent binding ability with respect to ionic strength. Eluants containing a high concentration of salt provide a greater modification of the adsorbent binding ability with respect to ionic strength.”

At Fig. 2, Hutchens teaches the use of 0.5 M and 1.0 M NaCl eluants:

Neither Short & Whittle nor Hutchens teach using a salt concentration of about 2 M NaCl.

Marchant, throughout the publication, and, for example, at page 5, line 20 through page 6, line 11; Abstract, teaches a method of modification of the surface of a substrate, such as polyethylene, by plasma polymerizing polar organic monomers, such as N-vinyl-2-pyrrolidone or allyl alcohol, onto the surface of the substrate to provide a film of a plasma generated polymer on the surface. At page 19, lines 5-6, Marchant teaches an attachment of high-affinity heparin onto polyethylene samples surface-modified by plasma polymerization. At page 14, lines 23-35, Marchant teaches that 3 M NaCl linear salt gradient elution of increasing ionic strength was used for column separation of three different heparin fractions with different affinity for antithrombin III: non-adsorbed heparin, low affinity heparin and high-affinity heparin.

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It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to select a salt concentration of about 500 mM NaCl to about 2 M NaCl from the 3 M NaCl linear salt gradient, taught by Marchant, and the 0.5 M and 1.0 M NaCl eluants, taught by Hutchens, for the selective disassociation of glucosaminoglycan from a plasma polymerized surface taught by Short & Whittle. Here, the skilled artisan could have arrived at the claim through routine experimentation on the optimum or workable ranges of the claim.

One of ordinary skill in the art, at the time the invention was made, would have been motivated to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for the selective disassociation of a glucosaminoglycan, because it would be desirable, to re-use the plasma polymerized surface, taught by Short & Whittle, or use it, for example, for investigation of ionic strength of carbohydrate-protein interactions, as taught by Hutchens.

One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because NaCl is routinely used in the standard ionic strength-based salt eluants, as taught by Hutchens. In addition, as taught by Marchant, use of the 3 M NaCl linear salt gradient elution of increasing ionic strength provides selective separation of carbohydrates, such as heparin polysaccharides.

Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Short et al.**, WO 2004/040308 A1, filed October 29, 2003,

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published May 13, 2004 (of record), as evidenced by **Dako** General ELISA Procedure, February 2002 (of record), in view of **Hutchens**, WO 98/59360, published 12/30/1998 (of record), and **Marchant**, WO 94/10938, published 05/26/1994 (of record).

This rejection is necessitated by Applicant's amendment.

Short et al., throughout the publication, and, for example, at pages 6, 8, and 13, teach how to make and use a plasma polymerized surface of an organic monomer, including an allylamine, for immobilization of carbohydrates, polypeptides, genomic DNA, and cells. **Short et al.** at page 3 through page 5; Claims 4-7; 11-12; 15-16; teach the surface comprising volatile acid, volatile amine, volatile alcohol, and volatile hydrocarbon, and the surface comprising a mixture of one or more compounds having functional groups with a hydrocarbon. **Short et al.** at page 1 teach heteropolysaccharide, including glycosaminoglycans, such as, hyaluronan, dermatan sulfate, chondroitin sulfate, heparin, heparan sulphate and keratan sulphate, and homopolysaccharide.

As to recitation "a salt concentration of about 500 mM NaCl to about 2 M NaCl," **Short et al.** at page 16 teach use of standard ELISA methods to wash the unbound heparin from the allylamine coated microtiter plates. According to MPEP 2131.01, extra references can be used to show the meaning of a term used in the primary reference. **Dako** General ELISA Procedure, February 2002 indicates that 0.15 M and 0.5 M NaCl concentrations are used in the standard coating and washing buffers for ELISA methods. A specific example in the prior art which is within a claimed range, here, 0.5 M NaCl concentration, anticipates the range. MPEP 2131.01.

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Short *et al.* do not teach using a salt concentration of from more than 500 mM NaCl to about 2 M NaCl.

Hutchens, throughout the publication, and, for example, in Abstract, teaches methods of retentate chromatography for resolving analytes in a sample, which methods involve adsorbing the analytes to a substrate under a plurality of different selectively conditions, and detecting the analytes retained on the substrate by desorption spectrometry. At page 7, line 9; page 21, line 15; Hutchens teaches the analyte to be an organic biomolecule, such as carbohydrate. At page 33, lines 1-9, Hutchens teaches washing the adsorbent with eluants. At page 33, lines 19-26, Hutchens teaches the use of ionic strength-based salt eluants:

“Eluants which modify the selectivity of the adsorbent with respect to ionic strength include salt solutions of various types and concentrations. The amount of salt solubilized in the eluant solution affects the ionic strength of the eluant and modifies the adsorbent binding ability correspondingly. Eluants containing a low concentration of salt provide a slight modification of the adsorbent binding ability with respect to ionic strength. Eluants containing a high concentration of salt provide a greater modification of the adsorbent binding ability with respect to ionic strength.”

At Fig. 2, Hutchens teaches the use of 0.5 M and 1.0 M NaCl eluants:

Neither Short *et al.* nor Hutchens teach using a salt concentration of about 2 M NaCl.

Marchant, throughout the publication, and, for example, at page 5, line 20 through page 6, line 11; Abstract, teaches a method of modification of the surface of a

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substrate, such as polyethylene, by plasma polymerizing polar organic monomers, such as N-vinyl-2-pyrrolidone or allyl alcohol, onto the surface of the substrate to provide a film of a plasma generated polymer on the surface. At page 19, lines 5-6, Marchant teaches an attachment of high-affinity heparin onto polyethylene samples surface-modified by plasma polymerization. At page 14, lines 23-35, Marchant teaches that 3 M NaCl linear salt gradient elution of increasing ionic strength was used for column separation of three different heparin fractions with different affinity for antithrombin III: non-adsorbed heparin, low affinity heparin and high-affinity heparin.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to select a salt concentration of about 500 mM NaCl to about 2 M NaCl from the 3 M NaCl linear salt gradient, taught by Marchant, and the 0.5 M and 1.0 M NaCl eluants, taught by Hutchens, for the selective disassociation of glucosaminoglycan from a plasma polymerized surface taught by Short *et al.* Here, the skilled artisan could have arrived at the claim through routine experimentation on the optimum or workable ranges of the claim.

One of ordinary skill in the art, at the time the invention was made, would have been motivated to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for the selective disassociation of a glucosaminoglycan, because it would be desirable, to re-use the plasma polymerized surface, taught by Short *et al.*, or use it, for example, for investigation of ionic strength of carbohydrate-protein interactions, as taught by Hutchens.

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One of ordinary skill in the art, at the time the invention was made, would have had a reasonable expectation of success for doing so because NaCl is routinely used in the standard ionic strength-based salt eluants, as taught by Hutchens. In addition, as taught by Marchant, use of the 3 M NaCl linear salt gradient elution of increasing ionic strength provides selective separation of carbohydrates, such as heparin polysaccharides.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4-25, and 33-38 of copending Application No. 10/533,063 (the ‘063 application), PG PUB 20060251693 in view of Schwarz *et al.* Glycobiology, 2003, vol.

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13, No. 11, p. 749-754 (Final Office Action dated 09/08/2010) and **Hutchens**, WO 98/59360, published 12/30/1998.

The '**063**' application claims a method to immobilize at least one type of carbohydrate molecule comprising the steps of: i) providing a monomer source comprising one or more organic compounds which are capable of polymerization; ii) creating a plasma of said monomer source; iii) contacting a surface with said plasma to provide a plasma polymer coated surface; iv) contacting said **plasma polymer coated surface** with at least one type of biologically active **carbohydrate** molecule in its native form, wherein the plasma polymer coated surface is not modified prior to contacting with said carbohydrate molecule in its native form; and v) incubating said plasma polymer coated surface with said carbohydrate molecule in its native form, whereby the carbohydrate molecule is passively adsorbed, in the absence of albumin or salts, on the surface and thereby immobilized, such that the carbohydrate molecule remains in its native form, is not contaminated and retains its biological activity.

Schwarz *et al.* teach a carbohydrate array for specific binding glycan-binding proteins. At page 753, Schwarz *et al.* teach washing the glycan array with high-salt buffer PBS-Tween, supplemented with 2 M NaCl.

Hutchens teaches that different concentrations of NaCl, for example, 0.5 M and 1.0 M NaCl, are routinely used in the standard ionic strength-based salt eluants for disassociation of organic biomolecules, such as carbohydrates, from the substrate surfaces.

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It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for selective dissociation of at least one biologically active carbohydrate molecule immobilized onto a binding surface by the method taught by the '063 application.

Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 85, 87, 90-94, 96, 102, 103, 108, 109, and 112-123 of copending Application No. **10/560,210** (the '**210** application), PG PUB 20060252046 in view of **Schwarz et al.** Glycobiology, 2003, vol. 13, No. 11, p. 749-754 (Final Office Action dated 09/08/2010) and **Hutchens**, WO 98/59360, published 12/30/1998.

The '**210** application claims a method for preparing a heterogenous binding surface on a substrate comprising: depositing **a plasma polymer on the substrate** using at least one **organic compound monomer** as a source of plasma, wherein the monomer is polymerisable, the monomer comprises an alkene containing up to 20 carbon atoms and the monomer has a vapor pressure of at least 6.6×10^2 mbar; and coating at least part of the plasma polymer deposit with **a binding entity** which comprises a carboxyl or an amine functional group, wherein the binding entity is selected from the group consisting of **cells**, metabolites, pharmaceutically active agents, proteins including hormones, antibodies, enzyme, receptor, macromolecules including **DNA, RNA, protein** fragments, peptides, polypeptides, ligands, proteoglycans, **carbohydrates**, nucleotides, oligonucleotides, toxic reagents and

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chemical species and wherein the organic compound monomer is selected from the group consisting of N-vinyl pyrrolidone, allyl alcohol, acrylic acid, octa-1,7-diene, **allyl amine**, perfluorohexane, tetraethyleneglycol monoallyl ether and hexamethyl disiloxane. (Emphasis added).

Schwarz et al. teach a carbohydrate array for specific binding glycan-binding proteins. At page 753, Schwarz *et al.* teach washing the glycan array with high-salt buffer PBS-Tween, supplemented with 2 M NaCl.

Hutchens teaches that different concentrations of NaCl, for example, 0.5 M and 1.0 M NaCl, are routinely used in the standard ionic strength-based salt eluants for disassociation of organic biomolecules, such as carbohydrates, from the substrate surfaces.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for selective dissociation of at least one biologically active carbohydrate molecule immobilized onto a binding surface by the method taught by the ‘**210** application.

Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 41, 47-50, and 54 of copending Application No. 10/509,431 (the ‘**431** application), PG PUB 20060166183 in view of **Marchant**, WO 94/10938 (Final Office Action dated 09/08/2010); **Schwarz et al.** Glycobiology, 2003, vol. 13, No. 11, p. 749-

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754 (Final Office Action dated 09/08/2010) and **Hutchens**, WO 98/59360, published 12/30/1998.

The '**431** application claims a method for preparing a **plasma polymerized surface** on a substrate comprising: depositing a plasma polymer on the substrate using at least one **organic compound monomer** as a source to produce a plasma which is emitted from a plasma source and from which the plasma polymer is deposited; and moving at least one of: (i) the plasma source, and (ii) the substrate, relative to one another during plasma deposition such that at least part of the substrate has a plasma polymer deposit that is non-uniform, wherein the substrate is separated from the plasma source by a mask plate having at least one aperture that defines features of the deposited plasma polymer surface, the mask plate being spaced from the substrate wherein the organic compound monomer is selected from the group consisting of allyl alcohol, acrylic acid, octa-1,7,-diene, **allyl amine**, perfluorohexane, tetraethyleneglycol monoalkyl ether or hexamethyldisiloxane. (Emphasis added).

Marchant, throughout the publication, and, for example, at page 5, line 20 through page 6, line 11; Abstract, teaches a method of modification of the surface of a substrate, such as polyethylene, by plasma polymerizing polar organic monomers, such as N-vinyl-2-pyrrolidone or allyl alcohol, onto the surface of the substrate to provide a film of a plasma generated polymer on the surface. At page 19, lines 5-6, Marchant teaches an attachment of high-affinity heparin onto polyethylene samples surface-modified by plasma polymerization. At page 14, lines 23-35, Marchant teaches that 3 M NaCl linear salt gradient elution of increasing ionic strength was used for column

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separation of three different heparin fractions with different affinity for antithrombin III: non-adsorbed heparin, low affinity heparin and high-affinity heparin.

Schwarz *et al.* teach a carbohydrate array for specific binding glycan-binding proteins. At page 753, Schwarz *et al.* teach washing the glycan array with high-salt buffer PBS-Tween, supplemented with 2 M NaCl.

Hutchens teaches that different concentrations of NaCl, for example, 0.5 M and 1.0 M NaCl, are routinely used in the standard ionic strength-based salt eluants for disassociation of organic biomolecules, such as carbohydrates, from the substrate surfaces.

It would have been *prima facie* obvious, at the time the invention was made, for one of ordinary skill in the art to use a salt concentration of about 500 mM NaCl to about 2 M NaCl for selective dissociation of at least one biologically active carbohydrate molecule immobilized onto a binding surface by the method taught by the '413 application.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed on 04/19/2011 have been fully considered but they are not persuasive.

I. The rejection of Claims 1, 6, 7, 12-16, 26, 28 and 31 under 35 U.S.C. 102(e) as being anticipated by Short *et al.*, as evidenced by Dako General ELISA Procedure, February 2002, is maintained. Applicant traversed Short *et al.* for not teaching selective disassociation of bound glycosaminoglycan from a plasma polymerized surface. As

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shown above, Short *et al.*, as evidenced by Dako General ELISA Procedure, February 2002, teach the use of an agent having a salt concentration of 500 mM NaCl to wash a plasma polymerized surface of an organic monomer including an allylamine for heparin adsorption assay. The examiner notes that a plasma polymerized surface taught by Short *et al.* is identical to the surface used in the claimed method of the present invention. Short *et al.* do not expressly teach the selective disassociation of bound heparin from a plasma polymerized surface. However, according to MPEP 2112.02, prior art device anticipates a claimed process if the device carries out the process during normal operation:

“Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. *In re King*, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986).”

II. The rejection of Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Short & Whittle, as evidenced by WO 98/19161, in view of Marchant, and Schwarz is maintained for the reasons set forth above. Applicant traversed Marchant and Schwartz for not teaching selective disassociation of bound glycosaminoglycan from a plasma polymerized surface. However, these references were used to demonstrate that it is well-known in the art to use eluants with various NaCl concentrations, e.g., 2M NaCl, for dissociation of glucosaminoglycans from surfaces/sorbents. The examiner notes that a plasma polymerized surface taught by

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Short & Whittle is identical to the surface used in the claimed method of the present invention.

III. The rejection of Claims 1, 6, 7, 12-16, 26, 28, 29 and 31 under 35 U.S.C. 103(a) as being unpatentable over Short & Whittle, as evidenced by WO 98/19161, in view of Hutchens and Marchant is maintained for the reasons set forth above. Applicant traversed Hutchens and Marchant for not teaching selective disassociation of bound glycosaminoglycan from a plasma polymerized surface. However, these references were used to demonstrate that it is well-known in the art to use eluants with various NaCl concentrations, e.g., 2M NaCl, for dissociation of glucosaminoglycans from surfaces/sorbents. The examiner notes that a plasma polymerized surface taught by Short & Whittle is identical to the surface used in the claimed method of the present invention.

IV. With regard to the provisional rejections of Claims 1, 6, 7, 12-16, 26, 28 and 31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1, 4-25 and 33-38 of co-pending U.S. Application No. 10/533,063, in view of Schwartz and Hutchens, WO 98/59360, published 12/30/1998; over Claims 85, 87, 90-94, 96, 102, 103, 108, 109 and 112-123 of co-pending U.S. Application No. 10/560,210, in view of Schwartz and Hutchens, WO 98/59360, published 12/30/1998; and over Claims 41, 47-50 and 54 of co-pending U.S. Application No. 10/509,431, in view of Marchant, Schwartz and Hutchens, WO 98/59360, published 12/30/1998, Applicant state that they will consider filing a terminal disclaimer. Therefore, these provisional rejections are maintained.

Conclusion

Claims 1, 6, 7, 12-16, 26, 28 and 31 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GALINA YAKOVLEVA whose telephone number is (571)270-3282. The examiner can normally be reached on Monday-Friday 8:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571)272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/G. Y./

Examiner, Art Unit 1641

/SHAFIQUL HAQ/

Primary Examiner, Art Unit 1641